REMARKS/ARGUMENTS

Claims 10-25, directed to methods of preparing a water-dispersible liquid vitamin food additive for animals, are pending the in the application. Claims 10-25 stand rejected. Reconsideration of the present application is requested in view of the following remarks.

At page 2 of the Office Action, the Examiner maintained the rejection of claims 10-25 under 35 USC 103(a) as being unpatentable over Kardys (U.S. Patent No. 3,932,634) in view of Tipton *et al.* (U.S. Patent 5,747,058). The basis for the rejection is that it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to modify the invention of Kardys in view of Tipton *et al.* into the objects of the instant application. In the present Office Action, the Examiner addressed Applicants' assertions that the present rejection is based upon improper hindsight reasoning. The Examiner emphasized that prior art can be relied upon for all that it teaches, whether such a disclosure is explicit, implicit or inherent and that, in his view, Tipton *et al.* points to an ever-present goal in the art of controlling the viscosity of emulsions and dispersions, particularly those that provide a medicinal or nutritional benefit for a subject, and that this reference shows a way of controlling the viscosity of such compositions through the use of solvents such as ethyl lactate. The Examiner concluded by stating that when the prior art is considered collectively, one of ordinary skill finds the motivation to combine the disclosures of the prior art with a reasonable expectation of success.

Applicants again traverse this rejection. The obviousness rejection made by the Examiner does not establish a *prima facie* case of obviousness with respect to the invention of claims 10-25. Kardys and Tipton *et al.* relate to two very different types of compositions. The Kardys patent teaches a vitamin composition for ingestion which

consists essentially of 25% to 55% by weight of an oil-soluble vitamin selected from the group consisting of vitamin A, vitamin D_2, vitamin D_3, vitamin E or combinations thereof, in water together with a specific dispersing agent which makes up about 35% to about 85% of the total composition. The Kardys patent does not teach or suggest the use of the use of an alkyl lactate in the preparation a vitamin composition, much less the preparation a water-dispersible liquid vitamin food additive for animals. Additionally, Kardys does not suggest the use of precursors of vitamins E and D3 as recited in the claimed methods.

By contrast, the Tipton *et al.* patent discloses compositions that form highly viscous depots when administered and are useful for the controlled release of substances. The compositions in Tipton *et al.* comprise a non-polymeric, non-water soluble high-viscosity liquid carrier material of viscosity of at least 5,000 cP at 37°C that does not crystallize neat under ambient or physiological conditions and a substance to be delivered. Column 5, lines 50-57 of Tipton *et al.* discloses mixing the high viscosity liquid carrier material with a viscosity lowering water soluble or water miscible solvent to form a lower viscosity liquid carrier material and then mixing the lower viscosity liquid carrier material with a substrate for controlled delivery. Column 10, lines 15-16 recite examples of suitable solvents, including ethyl lactate. As disclosed at column 10, lines 39-49, the compositions in Tipton *et al.* can be administered topically, systemically or parenterally. Systemic administration is further described as mucosal administration orally, rectally, vaginally or nasally. Column 10, lines 50-63 describe the compositions in greater detail and disclose that upon administration, the solvent dissipates forming a highly viscous depot. The compositions of Tipton *et al.* can be formulated as a mouthwash for topical oral delivery, but this type of formulation is very different from a formulation intended for ingestion. Tipton *et al.* discloses a number of substances that can be delivered by the depot formulation including vitamins, but does not disclose vitamin precursors which are used in the claimed methods.

The compositions produced by the methods disclosed in each of the cited references are suitable for different and distinct uses (i.e., for ingestion or for controlled-release of substances). Neither reference teaches that the composition of that reference is suitable for any other use. Accordingly, the teachings of the cited references are too different to be combined in the manner suggested by the Examiner.

Moreover, Kardys and Tipton *et al.* both relate to the field of pharmaceuticals (although Tipton *et al.* discloses that the compositions therein are also suitable for administration to animals and plants). By contrast the composition obtained from the claimed methods is used as a vitamin food additive for animals; i.e. a substance added to the natural ingredients that make up an animal's diet. The compositions of the present invention are intended for oral administration to animals only, whereas the formulations of Kardys and Tipton *et al.* are intended, at least in part, for pharmaceutical administration to humans. Kardys and Tipton *et al.* thus pertain to art that is non-analogous to the claimed methods and compositions formed by the claimed methods. The fields of animal nutrition and pharmaceuticals are different and persons skilled in these arts recognize that there are differences in, for example, the degree of purity of the ingredients used in the formulation and the need for sterilization of the composition before storage or use, that separate these fields from each other. Thus, persons skilled in the art would not look to the field of pharmaceuticals for preparation of an animal food additive.

Even if it was somehow possible to combine the cited references, the Examiner has not established that an artisan of ordinary skill would have been motivated to combine the cited references in the manner suggested by the Examiner. Kardys and Tipton *et al.* are unrelated, isolated pieces of prior art. In the present Office Action, the Examiner asserts that Tipton *et al.* points to an ever-present goal in the art of controlling the viscosity of emulsions and dispersions, particularly those that provide a medicinal or nutritional benefit for a subject, and that this reference shows a way of controlling the viscosity of such compositions through the use of solvents such as ethyl lactate.

The Examiner has only provided conclusory statements for why the invention of the present claims is obvious in view of the cited references. There is no explanation at all as to why an artisan of ordinary skill in the art would be motivated to combine the cited references in the manner suggested by the Examiner, except for the general conclusory statement that controlling viscosity is an ever-present goal. Still further, there is no explanation at all as to where in the cited references there are teachings or suggestions from which an artisan would find motivation to combine the references in the manner suggested by the Examiner.

In the previous Office Action mailed November 19, 2003, the Examiner pointed out portions of Tipton *et al.* that refer to lowering the viscosity of the composition (col. 5, lines 50-57 and column 10, lines 15-16), but, as discussed in Applicants' response to that Office Action, these portions of Tipton *et al.* fall far short of providing motivation to combine the teachings of the cited references. There is no suggestion or disclosure in Tipton *et al.* that a solvent such as ethyl lactate could or should be used to control the viscosity of a formulation that does not contain a high viscosity liquid carrier material, let alone a vitamin formulation as disclosed in Kardys.

In *In re Dembiczak* 50 USPQ2d 1614 (Fed. Cir. 1999), the Federal Circuit reversed a rejection of claims directed to plastic trash bags decorated to resemble a Halloween pumpkin as obvious on the grounds that the Examiner had not shown motivation for combining the references used to reject the claims. The Court stated that the Board had not established a *prima facie* case of obviousness because, although there was a discussion of the ways the multiple prior art references could be combined to read on the claimed invention, there was no demonstration of how the cited references taught or suggested their combination to yield the claimed invention, or any identification of a teaching, suggestion or motivation to combine the teachings of the cited references. Indeed, the Court stated that "[o]ur case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous

application of the requirement for a showing of the teaching or motivation to combine prior art references." *Id.*, at 1617.

In the instant application, the Examiner has also applied an improper hindsight-based obviousness analysis by citing to portions of Kardys and Tipton *et al.* that teach certain elements of the claimed invention and then stating that the combination of all of these elements would be obvious to obtain a formulation having the properties that are described in the present application. The teachings of the present invention regarding the desired properties of the formulation produced by the claimed methods cannot be used as part of the basis for an obviousness rejection. The cited references, by themselves, must teach or suggest the claimed invention and provide the motivation to combine the references in the manner necessary to produce the claimed invention. In the present rejection, the Examiner has not only failed to explain why or how the teachings of Kardys and Tipton *et al.* can be combined, the Examiner has also failed to explain how the teachings of the references, by themselves, would motivate an artisan to combine the teachings in a manner which would produce the presently claimed methods.

The present invention relates to methods for preparing water-dispersible liquid vitamin food additives for animals. These additives are introduced into animal feed to supplement the diet of the animal. Generally vitamins are added as a vitamin mix (i.e., a vitamin premix) in two ways. A powdered vitamin premix can be added to the animal feed, and the resulting mixture then formed into pellets. Alternatively, vitamins can be supplied in liquid form. A drawback of vitamin compositions is that vitamins are unstable and can decompose when exposed to high temperatures. Precursors of vitamins, which are used in the claimed methods, are more stable and will not lose their potency as readily as vitamins during storage, transport and inclusion with other products. The precursors of vitamins are converted to vitamins by the animal when ingested. Vitamins in the liquid form present the additional difficulty of finding the right solvent, suitable for oral administration of vitamins and permitting at the same time storage and transportation

of the vitamin composition. The use of alkyl lactates in the preparation of water-dispersible liquid vitamin food additives for animals overcomes these problems.

Accordingly, it is respectfully submitted that the Examiner has not established a *prima facie* case of obviousness. Claims 10-25 are therefore not obvious over Kardys in view of Tipton *et al.* Withdrawal of this section 103 rejection is requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is respectfully requested and an early Notice of Allowance is earnestly solicited.

Respectfully submitted,
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Date: July 25, 2005

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